JUL 17 2002

510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Daniel Tseng
K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: + 886 2 22991378
Facsimile: + 886 2 22991386

Date Prepared: June 5, 2002

Name of Device and Name/Address of Sponsor

Digital Clinical Thermometer Model KD-193

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: + 886 2 22991378
Facsimile: + 886 2 22991386
Contact Person : Daniel Tseng

Common or Usual Name	Digital Thermometer
Classification Name	Class II §880.2910 Clinical Electronic Thermometer
Predicate Device	I. K-jump Health Co., Ltd. K-jump Digital Clinical Thermometer II. Advanced Bioresearch Assoc. SureTemp® Electronic Thermometer

Intended Use/Indications for Use

The devices are intended to measurement the human body temperature, and specifically indicated to operate in either predictive mode or regular mode orally, rectally or under the arm.

Technology Characteristics

The device is an electronic thermometer with a hinged probe and an LCD display. The device was designed to measure human body predictive temperature (fast mode) around four seconds with predictive algorithm technology. If the predictive temperature cannot be measured, the device will take actual temperature (regular mode) automatically.

Performance Data

The Digital Clinical Thermometer model KD-193 complies with EN 60601-1-2 (1996); EN 55011 (1991); IEC 801-2(1991); IEC 801-3(1984) and the ASTM E1112-00 *Electronic Thermometer for Intermittent Determination of Patient Temperature* standard.

Substantial Equivalence

The device is substantially equivalent to K-jump's Digital Clinical Thermometer (K903590) and Advanced Bioresearch Assoc.'s SureTemp® Electronic Thermometer (K943695). The devices share the same intended use an indication for use and are technologically identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

K-Jump Health Company Limited
C/O Mr. Jonathan S. Kahan
Hogan & Harton L.L.P.
555 Thirteen Street, N.W.
Washington, D. C. 20004-1109

Re: K021851
Trade/Device Name: Digital Clinical Thermometer Model KD-193
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 5, 2002
Received: June 5, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if Known):_____

Device Name: Digital Clinical Thermometer Model KD-193

Indication for Use:

The Digital Clinical Thermometer Model KD-193 is intended to measure the human body temperature and is specifically indicated to operate in either predictive mode or regular mode orally, rectally or under the arm.

(PLEASE DO NOT WRITE BELOW THIS LINE---CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____ (Per 21 C.F.R. 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021851